

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application of:	)	
	)	
<b>Robert Rioux, et al</b>	)	<b>Group Art Unit:</b> Not-Yet-Assigned
	)	
<b>Serial No.:</b> Not-Yet-Assigned	)	<b>Examiner:</b> Not-Yet-Assigned
	)	
<b>Filed:</b> Herewith	)	
	)	
<b>For:</b> SYSTEMS AND METHODS FOR	)	
TREATING BREAST TISSUE	)	
	)	
	)	
	)	

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**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Alexandria, VA 22313-1450

Sir:

In accordance with 37 CFR § 1.97 and 1.98, the items identified in this Information Disclosure Statement (“IDS”) are brought to the attention of the Office. Copies of US Patents and US Patent Publications are not enclosed, pursuant to the US Patent & Trademark Office waiver of this requirement under 37 CFR § 1.98 (a)(2)(i) for patent applications filed after June 30, 2003. Copies of other cited references are enclosed.

The items identified in this IDS may or may not be “material” pursuant to 37 CFR § 1.56. The submission thereof by Applicant is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as “prior art” under 35 USC § 102 with respect to this invention unless specifically designated by Applicant as such.

**INFORMATION DISCLOSURE STATEMENT FILING PROVISION:**

☒ This IDS is believed to be timely in that it is being submitted under 37 CFR § 1.97(b), that is (1) within three months of the filing date of the application, which is not a continued prosecution application filed under § 1.53(d) or (2) within three months of entry of the national stage as set forth in 37 CFR § 1.491; or (3) before the mailing of a first Office action on the merits; or (4) before the mailing of a first Office action after filing a request for continued examination under § 1.114. Thus, no fee is required.

☐ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and charge the fee due under 37 CFR § 1.17(p) to the deposit account referenced below.

☐ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and a statement under 37 CFR § 1.97(e) is included below, thus no fee is required.

☐ This IDS is being submitted under 37 CFR § 1.97(c), that is after mailing of a first Office action on the merits, but before a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311.

☐ The fee due under 37 CFR § 1.17(p) is submitted herewith.

☐ A statement under 37 CFR § 1.97(e) is included below, thus no fee is required. In the event that this IDS is not received before a Final Action or a Notice of Allowance, then Applicant respectfully requests that the Office consider the filing of these papers to be submitted under 37 CFR § 1.97(d) and charge the fee due under 37 CFR § 1.17(p) to the deposit account below.

☐ This IDS is being submitted under 37 CFR § 1.97(d), that is after a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311, but before payment of the issue fee. A statement under 37 CFR § 1.97(e) is included below. The fee due under 37 CFR § 1.17(p) is submitted herewith.

**STATEMENT UNDER 37 CFR § 1.97(e):**

☐ Each item contained in this IDS was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS.

☐ No item contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this statement after making

reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this IDS.

**PAYMENT AND/OR AUTHORIZATION TO CHARGE FEES:**

- ☐ A check in the amount of \_\_\_\_\_ is enclosed for the above fee(s).
- ☐ Please charge \_\_\_\_\_ to Deposit Account No. **50-2518** for the above fee(s).
- ☐ Although applicant believes no fee is required, the Commissioner is authorized to charge any fees required by the filing of these papers, and to credit any overpayment to Bingham McCutchen's Deposit Account No. **50-2518**.

Respectfully submitted,  
BINGHAM McCUTCHEN LLP

Dated: Jan 27, 2004

By: DT Burse  
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Reg. No. 37,104

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	Not-Yet-Assigned
				Filing Date	Herewith
				First Named Inventor	Robert F. Rioux, et al
				Group Art Unit	Not-Yet-Assigned
				Examiner Name	Not-Yet-Assigned
				Attorney Docket Number	28-7034432001 (03-226)
Sheet	1	of	3		

U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	1.	5,345,948		O'Donnell, Jr.	09-13-1994	
	2.	5,774,260		Petitto et al	06-30-1998	
	3.	6,067,191		Petitto et al	05-23-2000	
	4.	6,168,779		Barsky et al	01-02-2001	
	5.	6,221,622		Love	04-24-2001	
	6.	6,261,246		Pantages et al	07-17-2001	
	7.	6,306,132		Moorman et al	10-23-2001	
	8.	6,313,946		Petitto et al	11-06-2001	
	9.	6,325,796		Berube et al	12-04-2001	
	10.	6,328,709		Hung et al	12-11-2001	
	11.	6,355,033		Moorman et al	03-12-2002	
	12.	6,391,026		Hung et al	05-21-2002	
	13.	6,405,073		Crowley et al	06-11-2002	
	14.	6,428,502		Lang	08-06-2002	
	15.	2001/0039416		Moorman et al	11-08-2001	
	16.	2002/0058932		Moorman et al	05-16-2002	
	17.	2002/0107579		Makino	08-08-2002	
	18.	2002/0160431		Love et al	10-31-2002	
	19.	2003/0187324		Gatto	10-02-2003	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sub>6</sub>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	20.	WO	00/16708		Windy Hill Technology, Inc.	03-30-2000		
	21.	WO	02/071991	A2	Jadeite Limited	09-19-2002		

Examiner Signature	Date Considered
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		Attorney Docket Number	28-7034432001 (03-226)		
Sheet	2	of	3		

OTHER DOCUMENTS -- NON PATENT LITERATURE			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	22.	ACUEITY "A Bigger Picture in Microendoscopy", <a href="http://www.acueity.com/pages/product2.html">http://www.acueity.com/pages/product2.html</a> 11/15/02	
	23.	ACUEITY "Early Detection – Breast Scope Technology May Help in Finding Cancer", <a href="http://www.acueity.com/pages/news7.html">http://www.acueity.com/pages/news7.html</a> 05/15/01	
	24.	ACUEITY "Scoping Out Breast Cancer", <a href="http://www.acueity.com/pages/news6.html">http://www.acueity.com/pages/news6.html</a> January 2001	
	25.	IMAGINIS, "Breast Cancer Diagnosis" Sponsored by Siemens, <a href="http://www.imaginis.com/breasthealth/ductal_lavage.asp">http://www.imaginis.com/breasthealth/ductal_lavage.asp</a> 11/15/02	
	26.	KIM, Julian, "Mammary Ductoscopy – Current and Future Applications" Cancernews, <a href="http://216.239.39.100/search?q=cache:wASQ5hBaTZCQ">http://216.239.39.100/search?q=cache:wASQ5hBaTZCQ</a> 11/15/02	
	27.	WITTEN, Celia "Miniature Endo/Laparoscopy" letter from the Department of Health and Human Services, 510(k) # K983527, dated 01/19/99	
	28.	THE CANCER CURE FOUNDATION "Laboratory Test that Detect Cancer" <a href="http://www.cancure.org/test_to_detect_cancer.htm">http://www.cancure.org/test_to_detect_cancer.htm</a> 11/15/02	
	29.	NAHLIELI, Oded "Endoscopic Technique for the Diagnosis and Treatment of Inflammatory Salivary Gland Diseases and for Minimal Temporomandibular-Joint Arthroscopy" The Barzilai Medical Center Ashkelon, Israel, STORZ endoscope, <a href="http://www.karlstorz.com/np-speid.htm">http://www.karlstorz.com/np-speid.htm</a>	
	30.	AETNA "Breat Ductal Lavage and Fiberoptic Ductoscopy" Coverage Policy Bulletins Number 0517, <a href="http://www.aetna.com/cpb/data/CPA0517.htm">http://www.aetna.com/cpb/data/CPA0517.htm</a> , 11/01	
	31.	HERZOG SURGICAL "Ductoscopy" <a href="http://www.herzosurgical.com/ductoscopy.htm">http://www.herzosurgical.com/ductoscopy.htm</a> , 11/15/02	
	32.	METHODIST HEALTH CARE SYSTEM "Breast Health Healthy Knowledge" <a href="http://www.methodisthealth.com/news/breast/November2000.htm">http://www.methodisthealth.com/news/breast/November2000.htm</a> , 11/2000	
	33.	MEDICAL STAFF UPDATE "Physician turns love of the ocean into eclectic career" Stanford Hospital and Clinics, <a href="http://www-med.Stanford.edu/shs/update/archives/JUL2002/newman.html">http://www-med.Stanford.edu/shs/update/archives/JUL2002/newman.html</a> 11/21/02	
	34.	DONOWAY, Robert "Leader in Intraductal Breast Surgery" M.D. News Ft. Lauderdale/ Broward County October 2002	
	35.	MOKBEL Kefah "The evolving Role of Mammary Ductscopy" Medscape, Curr Med Res Opin 18 (1):30-32, 2002; <a href="http://www.medscape.com/viewarticle/429688">http://www.medscape.com/viewarticle/429688</a>	

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<div style="float: left; width: 40%;"><p>Substitute for form 1449A/PTO</p> <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2><p style="text-align: center;"><i>(use as many sheets as necessary)</i></p></div> <div style="float: right; width: 60%; border: 1px solid black; padding: 5px;"><p style="text-align: center;"><b>Complete if Known</b></p><table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%;">Application Number</td><td style="width: 50%;">Not-Yet-Assigned</td></tr><tr><td>Filing Date</td><td>Herewith</td></tr><tr><td>First Named Inventor</td><td>Robert F. Rioux, et al</td></tr><tr><td>Group Art Unit</td><td>Not-Yet-Assigned</td></tr><tr><td>Examiner Name</td><td>Not-Yet-Assigned</td></tr><tr><td>Attorney Docket Number</td><td>28-7034432001 (03-226)</td></tr></table></div>				Application Number	Not-Yet-Assigned	Filing Date	Herewith	First Named Inventor	Robert F. Rioux, et al	Group Art Unit	Not-Yet-Assigned	Examiner Name	Not-Yet-Assigned	Attorney Docket Number	28-7034432001 (03-226)
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36.	JAMA "Endoscopic Visualization of Breast Tumors" research letters Vol 284, No. 12, September 27, 2000, <a href="http://www.jama-ama-assn.org/issues/v284n12/full/jlt0927-6.html">http://www.jama-ama-assn.org/issues/v284n12/full/jlt0927-6.html</a>	
37.	WITTEN, Celia "ViaDuct™ MicroEndoscope and Accesories" letter from the Department of Health and Human Services, # K011189, dated 07/16/2001	
38.	7NEWS BOSTON "Breakthrough Breast Test" <a href="http://www.whdh.com/feature/articles_p/healthcast/H653">http://www.whdh.com/feature/articles_p/healthcast/H653</a> 11/15/02	
39.	ASIN, Stefanie "Camera May Help Detect Breast Cancer" Texas Medical Center News" Vol. 23, No. 22, 12/01/2001, <a href="http://www.tmc.edu/tmcnews/12_01_01/page_12.html">http://www.tmc.edu/tmcnews/12_01_01/page_12.html</a>	

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